

Dueling Diseases: The Race for Cure Dollars

By Melissa Attias, CQ Staff

They come with colored ribbons, celebrity advocates and heart-rending stories of loved ones who've persevered in the face of fatal diagnoses. As Congress assembles its budgets and spending bills, patient advocacy groups for specific diseases issue public pleas for more money for medical research — nothing as unseemly as earmarks or carve-outs, but general support for the National Institutes of Health and other politically popular health causes that tend to foment bipartisan comity.

Behind the scenes, however, the veneer of collegiality that these groups display during their rounds on Capitol Hill is cracking. Groups are jockeying to prioritize their particular diseases and stay on offense, anticipating that tight budgets brought about by the budget sequester could force lawmakers to choose between spending on Alzheimer's and HIV/AIDS or squelch funding for some promising line of cures.

The competing pleas and accompanying dire warnings about the consequences of inaction can test the patience of lawmakers, who have to sort through the emotional rhetoric.

"They're like a whining bunch of kids saying 'I want the next piece of cake,'" says former Republican Rep. Jack Kingston of Georgia, who chaired the House panel with jurisdiction over most discretionary health care spending in the 113th Congress. "They don't coordinate at all."

Raising the stakes is the 2011 law that capped the discretionary pool of money that the NIH shares with other nondefense agencies through fiscal 2021. Though the bipartisan budget deal struck in 2013 by GOP Rep. Paul D. Ryan of Wisconsin and Democratic Sen. Patty Murray of Washington eased some of the pain by lifting the sequester-level caps for two years, that relief runs out in October. The \$493.5 billion cap for fiscal 2016 would essentially freeze spending levels for the third year in a row, giving the NIH's \$29.4 billion discretionary budget little room to grow.

The popular research agency may yet get a reprieve. Lawmakers could strike another budget deal that funnels more money to scientists. Or Congress could clear a package approved unanimously last month by the House Energy and Commerce Committee that includes an extra \$10 billion in mandatory funding for the NIH over five years.

But if those efforts fall short, tension among advocacy groups could publicly fracture the medical research movement. While there's optimism the unified approach can prevail, it could fizzle out if advocates find it's not effective.

"The longer sequestration goes on and the fiercer competition becomes, it does get harder to hold people together," says Emily Holubowich, executive director of the public health nonprofit Coalition for Health Funding. "It can go from 'all for one and one for all' to 'every man for himself.'"

Disease Wars

Two constituencies already feeling some friction could be quickly pitted against each other under such circumstances. HIV/AIDS has been singled out this year by at least two Republican appropriators who suggest it's getting a disproportionately large share of funding while Alzheimer's disease is being neglected.

NIH Appropriations

"We have, in essence, converted it from a uniformly fatal disease to a rarely fatal disease," says Rep. Andy Harris of Maryland, alluding to the multi-drug cocktails that made HIV/AIDS manageable in developed countries. "It's time for the NIH to decide whether or not it's time to move on to another disease to cure, like Alzheimer's."

NIH Director Francis Collins says the manner in which his agency distributes money to specific diseases is complicated and constantly changing, with public health need, degree of disability and scientific opportunity all considered. But he also says basic science that is not paired with a particular condition has been foundational and makes up half the budget.

"I would not want to downgrade the importance of basic science," Collins says.

Congressional interest in targeting resources for medical research surged in the years after World War II, when the battlefield successes of penicillin prompted interest in other areas of medicine, according to former NIH historian Victoria Harden. The 1944 Public Health Service Act provided new authority to award grants to scientists and laid the foundation for Congress to add more specialized centers under the NIH umbrella. The agency's budget swelled from \$8 million in fiscal 1947 to more than \$1 billion by fiscal 1966.

As funding grew, policymakers began propelling certain diseases to the top of the agenda.

Spurred by the lobbying efforts of Mary Lasker and other pioneering advocates, President Richard Nixon signed the National Cancer Act in 1971, launching what would become known as the War on Cancer. Congress went on to boost appropriations for the National Cancer Institute from \$181 million in fiscal 1970 to more than \$1 billion in fiscal 1984.

Activists also helped shine the spotlight on the HIV/AIDS epidemic in the 1980s and 1990s, although the research and support dollars didn't begin flowing immediately. The disease's prevalence among the gay community and intravenous drug users gave it a taint during the early years that began to lift, in part, through attention on patients like Ryan White, an Indiana teen who contracted AIDS through a blood transfusion and died in 1990.

Deferring to NIH

While Congress has honed in on specific diseases in times of crisis, Connecticut Rep. Rosa DeLauro says the modus operandi passed down by both Democratic and Republican appropriators has been to leave it up to the NIH to identify the best scientific opportunities.

"As our rule of thumb, what we don't do is to earmark funding for particular illnesses," says DeLauro, the top Democrat on the Labor-HHS-Education Appropriations Subcommittee. "That would get us into picking and choosing, and we're not scientists."

Kingston, the former appropriator, says lawmakers are generalists who don't have the ability to get into the specifics of one disease versus another. He's now a principal for Squire Patton Boggs, which has a number of health care clients.

"There's a constituency for every disease," Kingston says. "Once you get in there, there's no end to it."

Indeed, the Institute of Medicine as far back as 1998 was flagging how congressional intervention had caused problems. An IOM report cited appropriators' decision in fiscal 1993 to direct extra money to breast, ovarian, cervical and prostate cancers through report language. That prompted cuts to other cancer research areas. Two years earlier, money designated for pediatric AIDS clinical trials led to reductions in vaccine development, among other things.

Beyond the NIH, Congress has funded disease-specific programs throughout the federal bureaucracy. Harris, a physician who sits on the same spending panel as DeLauro, says their proliferation is another reason for the research community to re-examine how money is allocated. As an example, he points to the Defense Department's research on amyotrophic lateral sclerosis, known as ALS or Lou Gehrig's disease, which is congressionally funded at \$7.5 million for fiscal 2015.

"Although ALS research is fine to do, the question is whether it should be done at the Department of Defense," Harris says. Senate Armed Services Chairman John McCain, an Arizona Republican, has also criticized tapping the Defense budget for health research, saying it should be left to the Health and Human Services Department.

Over his nearly six-year tenure heading NIH, however, Collins says the agency has been "blessedly" saved from most earmarking activity. While the overall budget has been constrained, he says Congress tends to defer to the administration's wishes for distributing funds to the NIH's 27 constituent institutes and centers.

Former Rep. John Edward Porter, who presided over the health appropriations panel for six years before his retirement in 2001, says members would typically contact the NIH to lay out their plans and ensure they were scientifically useful. The Illinois Republican helped lead the successful movement to double NIH funding and now serves as chairman of Research!America, a research advocacy alliance, and advises health clients at the law firm Hogan Lovells.

"The worst thing that could ever happen is that you fund according to the largest lobby and the other diseases, very small diseases ... they get no funds," Porter says.

Setting Priorities

But appropriators still have ways to communicate their priorities in a less rigid manner.

Some of the institutes are focused on categories of diseases, for example, and lawmakers can send extra resources their way. Collins also says the NIH pays close attention to nonbinding report language that accompanies appropriations bills, viewing it as a thoughtful way for Congress to express ideas without being prescriptive.

Appropriators combined both of those techniques in the fiscal 2015 year-end spending bill when they noted in their explanatory statement that they expect “a significant portion” of a \$25 million increase for the National Institute on Aging to be used for Alzheimer’s research. They employed the same technique the year before, providing a \$100 million increase.

“In keeping with longstanding practice, the agreement does not recommend a specific amount of NIH funding for this purpose or for any other individual disease,” appropriators wrote. “Doing so would establish a dangerous precedent that could politicize the NIH peer review system.”

One of the more aggressive lobbies, Alzheimer’s groups have been particularly successful in getting around disease-specific hesitancy. NIH spending on Alzheimer’s rose by 25 percent from fiscal 2011 to 2014, and inquiries about the disease are a staple at hearings on medical research.

The pitch is a powerful one: Alzheimer’s and other forms of dementia will cost taxpayers \$153 billion this year through Medicare and Medicaid, and it’s the only one of the top 10 causes of death that can’t be prevented, cured or slowed. Death rates are rising, while heart disease and cancer have seen their rates go down.

But groups such as the Alzheimer’s Association aren’t the only lobbies armed with compelling arguments.

Advocates for patients with pancreatic cancer used estimates of a 6 percent to 7 percent survival rate to help propel a research bill for the deadliest cancers through Congress in 2012, which was initially focused on pancreatic cancer and then expanded to secure broader support.

A lack of precise statistics about how many people have Parkinson’s disease and its projected annual price tag of more than \$14 billion for medical expenses and indirect costs have advocates pushing for Congress to create a national data collection system for neurological diseases.

And with as many as one in three U.S. adults projected to have diabetes by 2050, advocates for patients with that illness are asking for a \$317 million increase in fiscal 2016 for the National Institute of Diabetes and Digestive and Kidney Diseases.

Gina Gavlak, national advocacy committee chairwoman for the American Diabetes Association, says her group emphasizes the rising economic costs of diabetes to counter responses from Capitol Hill about the multitude of disease groups looking for money. While their advocates try not to pit diabetes against another condition, she acknowledges that there is a sense of competition.

“I think anybody from any group that’s representing any kind of health-care issue or disease is going to say the same thing,” Gavlak says. “We’re told that by Congress constantly.”

Common Goals

That sort of feedback has helped some lobbies conclude that they’ll get more accomplished by working together on common goals than they would on their own.

Ted Thompson, CEO of the Parkinson's Action Network, says health groups have united behind the push to boost overall NIH funding with the assumption that a portion of the increase will trickle down to help their constituency. Collectively, advocates also want to see the best research funded, he says, noting that work on Alzheimer's could end up yielding a cure for Parkinson's.

Thompson's organization is a member of the Coalition for Health Funding, which advocates for more investment at the NIH, the Centers for Disease Control and Prevention, the Health Resources and Services Administration and other agencies. Another coalition — United for Medical Research — is singularly focused on boosting money for the NIH.

Cancer interests have also organized into the One Voice Against Cancer coalition, which a member of the cancer advocacy community says was established in direct response to the challenges of keeping different groups on the same page. The community was extremely fractured before its launch, the advocate says, but now it has a fairly unified message on appropriations in an effort to be more effective.

At the same time, some of the members of the broader alliance are also part of the Deadliest Cancers Coalition that focuses on cancers with five-year survival rates below 50 percent, as defined under the recent research bill. Those kinds of partitions set up the potential for friction between advocates for patients with the most aggressive cancers such as pancreatic and more treatable ones like breast cancer.

Scott Lilly, who spent 31 years on Capitol Hill, including a stint as Democratic staff director for the House Appropriations Committee, says some national advocacy networks are still missing the bigger picture: that the sequester-level caps are squeezing the discretionary spending pot they rely on for funding.

"I think they are far less effective in terms of the ultimate result because they don't recognize the box that they're in," says Lilly, now a senior fellow at the liberal Center for American Progress. "Rather than team up and work together with those in the same box, they tend to try to outdo each other."

Concern Over Priorities

While NIH funding has remained relatively stagnant since Congress doubled the agency's budget between fiscal 1998 and 2003, the caps on discretionary money have made a significant boost through the traditional appropriations process nearly impossible. Any extra money for the NIH comes at another agency's expense.

That strain has also renewed scrutiny over how the NIH prioritizes its funding. The current target is money allocated for HIV/AIDS research, with lawmakers challenging whether some of those funds would be better spent on Alzheimer's disease.

At a Senate Appropriations subcommittee hearing in April, Louisiana Republican Bill Cassidy raised eyebrows in the advocacy community when he specifically compared spending on each of the two conditions and said there seems to be "a total out of whack" of priorities.

"Are we going to wait until we figure out a vaccine for HIV/AIDS before we begin shifting to the new battle?" asked Cassidy, a physician.

According to NIH estimates, the agency spent nearly \$3 billion on HIV/AIDS-related research in fiscal 2014 and \$562 million on Alzheimer's, although it warns that the AIDS figure is reported differently and not directly comparable to other diseases. While there is no official requirement, about 10 percent of the overall NIH discretionary budget is traditionally reserved for HIV/AIDS.

Collins told Cassidy that his team is examining the disease's portfolio "with more scrutiny than ever." At the same time, Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, noted that infectious diseases have different considerations than other diseases that do not have the potential to be eradicated.

Carl Schmid, deputy executive director of the AIDS Institute, says advocates are very concerned that AIDS is being singled out. While it's good to ensure funding is prioritized, he says, critics are focusing on the disease burden in the United States rather than the global implications.

"I know other disease groups want increased funding," Schmid says. "We just hope they're not attacking HIV to get that."

Alzheimer's advocates, meanwhile, say the condition has been significantly underfunded for years and that Congress is right to focus on it. Donning purple sashes, they fill the halls of Capitol Hill for advocacy events backed by their "celebrity champions" such as actor Seth Rogen, who testified at a Senate hearing last year on the economic costs of the disease.

"The Alzheimer's Association understands that Congress has to make difficult choices and encourages prioritization where the burden is the greatest and where promising, targeted research stands ready for funding," says Robert J. Egge, the group's executive vice president of government affairs.

Sequestration's Effects

Similar concerns about research priorities swirled during the congressional budget battles of the 1990s, with lawmakers again honing in on HIV/AIDS as a target. Opportunities for scientific breakthroughs and spikes in prevalence or mortality rates for certain conditions can also drive the debate.

But the concerns have become acute in the era of sequestration. Collins kicked off his testimony at the Senate hearing by outlining the steps the agency is taking to ensure it's a good steward of taxpayer dollars. Requirements for strategic plans were included in the fiscal 2015 spending law and the version of the so-called 21st Century Cures package (HR 6) approved 51-0 by the Energy and Commerce panel in May.

"Certainly the very difficult budget situation is accelerating the impatience that everybody feels," Collins says. "I think the Alzheimer's disease advocacy organizations have been particularly vocal and I understand exactly why."

Absent another budget deal, other advocates could try to mimic the achievements of Alzheimer's by initiating a bolder approach. The competition glimpsed between HIV/AIDS and Alzheimer's interests could become a trend in the disease community, rather than an exception.

"I don't think it's broken out, but I think it's simmering under the surface," Lilly says, referring to the general rivalry between disease groups.

Continued frustration with research priorities could also convince lawmakers to change their approach. Sen. Jerry Moran, a Kansas Republican, told Collins at the Senate hearing that many people afflicted by different diseases ask Capitol Hill to help the NIH find cures for their conditions. While Congress has traditionally deferred decisions about research priorities to the NIH, he warned that he needs assurances that the agency is making the best decisions possible.

"If you don't do that prioritization," Moran said, "then I think it's going to become incumbent upon Congress to make decisions that are better made by you."